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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 559,622	04 27 2000	Rajesh Ranganathan	01997 521002	1966

7590 12 19 2001

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[REDACTED] EXAMINER

WOITACH, JOSEPH T

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1632

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/559,622	RANGANATHAN ET AL.
	Examiner Joseph Woitach	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 April 2000.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 1-8, 10 and 12-21 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 9 and 11 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 27 April 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4

4) Interview Summary (PTO-413) Paper No(s) _____
5) Notice of Informal Patent Application (PTO-152)
6) Other 6

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FEB 11 2000

DETAILED ACTION

This application filed April 27, 2000, claims benefit to provisional application 60/131,149, filed April 27, 1999.

Election/Restriction

Claims 1-21 are pending. Applicant's election without traverse of group V, claims 9 and 11, in Paper No. 11 is acknowledged. Claims 1-8, 10 and 12-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Claims 9 and 11 are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The disclosure is objected to because of the following informalities: The Brief Description of the Figures does not comply with 37 CFR 1.74. Specifically, a separate reference to and brief description of each of the drawing(s) must be present in the disclosure.

Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 9 is vague and incomplete. Claim 9 is drawn to a method for identifying a compound that modulates a serotonin-gated anion channel, however, final step (b) is only an assay step and there is no positive step indicating the correlation of a change in biological activity with a compound's ability to modulate a serotonin-gated anion channel. Further, a compound is administered 'to a serotonin-gated anion channel', and it is unclear what biological activity is being measured. In light of the teachings of the specification, binding of a compound can be assayed when a compound is added to serotonin-gated anion channel protein, however biological activity can only be measured in the context of a cell or organism. More clearly indicating the method steps and activity measured will obviate the basis of the rejection.

Claim 11 is vague and incomplete. Claim 11 is drawn to a method for characterizing a drug associated with serotonin-mediated response, however, the final step is only an assay step and there is no positive step indicating the correlation between modulation of activity associated with serotonin-gated anion channel and a specific characteristic of a drug. There is no

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antecedent basis for ‘the activity’ recited in the claim, and it is unclear what activity is modulated or what activity would be associated with or provide characterization of the drug. More clearly indicating the method steps and activity measured will obviate the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Scroggin *et al.* (IDS ref. Am. J. Physiol, Dec 1998).

Claims 9 and 11 are drawn to methods of identifying compounds and characterizing drugs for their effect on a biological activity mediated by a serotonin-gated anion channel comprising administering a compound/drug and assaying a modulation in the biological activity. The claims are drawn broadly to an assay of any activity and are not restricted to assaying any specific serotonin-gated anion channel. Further, there is no limitation that the compound/drug must directly affect the serotonin-gated anion channel and may act through other intermediate signal transduction pathway members. Scroggin *et al.* teach several compound and drugs which affect a

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serotonin mediated effect. For example, in figure 1A the amount of 5-HT is tested for its effect on excitatory response. Further, figures 1B and 2 other compounds, salts, agonists, antagonists, are tested and their ability to affect a change in a serotonin-gated anion channel is measured. A summary of the methodology used in Scroggin *et al.* teaches that a compound/drug is administered and a biological activity is measured. Thus, each of the method steps recited in the claims are taught by Scroggin *et al.* Therefore, the teachings of Scroggin *et al.* anticipate the claims.

Claims 9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Ali *et al.* (IDS reference J. Physiol. May 1998).

Claims 9 and 11 are summarized above. Ali *et al.* teach the administration of 5-HT, dbcAMP and Rp-cAMP and their effect on net voltage response on Cl⁻ activity. A summary of the methodology used in Ali *et al.* teaches that a compound/drug is administered and a biological activity is measured. Thus, each of the method steps recited in the claims are taught by Scroggin *et al.* Therefore, the teachings of Scroggin *et al.* anticipate the claims.

Claims 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Montigny *et al.* (IDS reference Science, 1978).

Claims 9 and 11 are summarized above. Montigny *et al.* teach the administration of 5-HT and several other compounds/drugs and their effect on action potentials (figure 1) and mean coulomb firing (figure 2). Ali *et al.* do not specifically state that serotonin-gated anion channels

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are affected, however whole regions of the brain are assayed, and Ali *et al.* teach that the measured responses were not all due to monoaminergic (page 1303; middle of second column). A summary of the methodology used in Ali *et al.* teaches that a compound/drug is administered and a biological activity is measured^(). Thus, each of the method steps recited in the claims are taught by Ali *et al.* Therefore, the teachings of Ali *et al.* anticipate the claims.

Claims 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Garner *et al.* (IDS reference Eur. J. Pharm., 1993).

Claims 9 and 11 are summarized above. Garner *et al.* teach the administration of 5-HT and ritanserin and their effect on action potentials of Cl- channels (abstract and potentials measured in figure 3). A summary of the methodology used in Garner *et al.* teaches that a compound/drug is administered and a biological activity is measured^(). Thus, each of the method steps recited in the claims are taught by Garner *et al.* Therefore, the teachings of Garner *et al.* anticipate the claims.

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ranganathan, R. *et al.* Nature 408:470-475, 2000.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach, whose telephone number is (703) 305-3732.

If attempts to reach the examine by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608.

An inquiry of a general nature or relating to the status of the application should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Joseph T. Woitach

**DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1600/1630**

Deborah Crouch